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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/841,325	04/24/2001	Mark Modell	MDS-009CN (6219/15)	6590

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EXAMINER

SMITH, RUTH S

ART UNIT	PAPER NUMBER
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3737

DATE MAILED: 04/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/841,325	Applicant(s) MODELL ET AL. ✓	
	Examiner Ruth S. Smith	Art Unit 3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 105-111, 113, 115-119, 121-126, 148, 150, 152-156, 159, 160, 162-168, 170 and 171 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>3/20/06</u> | 6) <input type="checkbox"/> Other: _____ |

Continuation of Disposition of Claims: Claims pending in the application are 105-111,113,115-119,121-126,148,150,152-156,159,160,162-168,170 and 171.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 20, 2006 has been entered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 105-111, 113, 115-119, 121-126, 148, 150, 152-156, 159, 160, 162-168, 170, 171 are rejected under 35 U.S.C. 103(a) as being unpatentable over DeBaryshe et al in view of Furler et al, or Saab or Choi et al. DeBaryshe et al disclose an optical system for analyzing tissue including means for illuminating and collecting optical radiation. The illuminating means and detecting means includes arrays and moveable mirrors and field stops as set forth in the claims. The system can analyze cervical tissue. Furthermore, the use of protective covers or disposable probes in the medical field is a well known expedient in order to prevent contamination. Examples of such are seen in Furler et al, Saab and Choi et al which disclose the use of a disposable sheath around a medical device to prevent contamination from one patient to another. It would have been obvious to one skilled in the art to have modified DeBaryshe et al such that system components comprise a disposable device such as a sheath in order to protect the patient from possible contamination. With respect to claim 119, the specific structure used to separate the wavelengths of the detected light would have been an obvious design choice of known equivalents in the art.

Claims 105-107, 109, 110, 115, 125, 126, 152-156, 159-160, 165-167, 170, 171 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zavislan (6,424,852) in view of Furler et al or Saab or Choi et al. Zavislan discloses an optical system for diagnosing tissue using an illuminating and detecting arrangement. Zavislan fails to specifically disclose the use of a disposable device to protect the patient during scanning, however, the elements shown in figures 9-11 which prevent the imager 83 from contacting the tissue can comprise a disposable device such as a sheath. The sheath is capable of being used only a single time and can be disposed of. The imager used in the apparatus of Zavislan is disclosed as that of US Patent No. 5,788,639 which includes beam splitters/mirrors which are moveable with respect to the patient. Furthermore, the use of protective covers or disposable probes in the medical field is a well known expedient in order to prevent contamination. Examples of such are seen in Furler et al, Saab and Choi et al which disclose the use of a disposable sheath around a medical device to prevent contamination from one patient to another. It would have been obvious to one skilled in the art to have modified Zavislan such that the elements shown in figures 9-11 which prevent the imager 83 from contacting the tissue can comprise a disposable device such as a sheath in order to protect the patient from possible contamination.

Claims 108, 111, 113, 118, 119, 121, 123, 148, 150, 162, 168 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zavislan in view of Furler et al or Saab or Choi et al as applied to claims 105, 107, 152 above, and further in view of Kittrell et al. Zavislan fails to disclose comparing the data obtained to a standard and the use of moveable mirrors to scan the tissue. It is well known in the medical art to obtain data from a tissue region and compare the data to at least one standard in order to properly diagnose the tissue region being tested. An example of such is seen in Kittrell et al. Kittrell et al disclose a method of optically analyzing tissue. Kittrell et al disclose illuminating the tissue using an optical assembly comprising moveable mirrors to focus the light on different regions of tissue. The structure set forth in claim 118, 119 is seen

in figure 23, elements 68,70. It would have been obvious to one skilled in the art to have further modified Zavislan such that the data obtained is analyzed by comparing such to a known standard in order to provide a diagnosis of the tissue being tested. Furthermore, it would have been obvious to have scanned the tissue sample by using moveable mirrors rather than mechanically translating the imager. Such a modification involves the substitution of one known type of scanning means for another. With respect to claim 121 and 162, the specific field stop dimension used would have been an obvious design choice of known equivalents in the art.

Claims 116,117,122,124,163,164 rejected under 35 U.S.C. 103(a) as being unpatentable over Zavislan ('852) in view of Furler et al or Saab or Choi et al and Kittrell et al as applied to claims 105, 108,152 above, and further in view of Raz. Raz discloses a confocal imaging system which uses an array of emitters and detectors in order to scan a large region of interest. It would have been obvious to one skilled in the art to have further modified Zavislan such that an array of detectors is used in order to scan a larger region of interest in a short time period. Inasmuch as Zavislan discloses the use of optical devices, the array of detectors would require the use of optical elements and processors. The use of an array of detectors and emitters would result in an array of field stops.

Response to Arguments

Applicant's arguments filed March 20, 2006 have been fully considered but they are not persuasive. It should be noted that it is a well known expedient in the medical art to use either disposable covers or probe to prevent contamination from occurring. Furthermore, it should be noted that any component of an apparatus is considered to be disposable. Therefore, the use of a one-time use sheath or probe is any type of medical apparatus is not considered to be a patentable feature.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth S. Smith whose telephone number is 571-272-4745. The examiner can normally be reached on M-F 7:30 AM-4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Ruth S. Smith
Primary Examiner
Art Unit 3737

RSS